Nos. 2017-1480

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

AMGEN INC.; AMGEN MANUFACTURING LIMITED; AMGEN USA, INC.,

Plaintiffs-Appellees,

v.

SANOFI; AVENTISUB, LLC; REGENERON PHARMACEUTICALS INC.; SANOFI-AVENTIS U.S., LLC,

Defendants-Appellants.

Appeal from the United States District Court for the District of Delaware, Case No. 1:14-cv-01317-SLR.
The Honorable **Sue L. Robinson**, Judge Presiding.

REPLY MEMORANDUM IN FURTHER SUPPORT OF MOTION FOR LEAVE TO FILE AMICI CURIAE BRIEF

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CERTIFICATE OF INTEREST

Pursuant to Federal Circuit Rules 28(a)(1) and 47.4(a), counsel for the *Amici Curiae* certifies the following:

1. The full name of every party or amicus represented by me is:

Dr. Luis Aparicio, MD; Dr. W. Ross Davis, MD; Dr. Avichai Eres, MD; Dr. Norman Lepor, MD; Dr. Mary McGowan, MD; Dr. Narendra Singh, MD; Dr. Paul Thompson, MD; Rosa DeBernardo; and Alina Wilson.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

None.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

None.

4. The names of all law firms and the partners or associates that appeared for the party or amici now represented by me in the trial court or agency or are expected to appear in this court are:

Boies Schiller Flexner LLP: William D. Marsillo and Michael D. Jay.

TABLE OF CONTENTS

CERTIFICATE OF INTEREST i

TABLE OF CONTENTS ii

TABLE OF AUTHORITIES iii

ARGUMENT 1

I. AMICI'S VIEWS ARE DESIRABLE, RELEVANT TO THE APPEAL, AND DO NOT IMPROPERLY SUPPLEMENT THE RECORD 3

II. AMICI WILL PROVIDE THIS COURT WITH UNIQUE AND IMPORTANT PERSPECTIVES IN WEIGHING THE MERITS OF THE INJUNCTION ISSUED BY THE DISTRICT COURT 8

TABLE OF AUTHORITIES

CASES

Casitas Mun. Water Dist. v. United States,
556 F.3d 1329 (Fed. Cir. 2009) 5

Chrysler Corp. v. United States,
604 F.3d 1378 (Fed. Cir. 2010) 4

CW Gov't Travel, Inc. v. United States,
163 F. App'x 853 (Fed. Cir. 2005) 5

Fluor Corp. & Affiliates v. United States,
35 Fed. Cl. 284 (1996) 3

GPX Int'l Tire Corp. v. United States,
422 F. App'x 887 (Fed. Cir. 2011) 4

Ladd v. United States,
646 F.3d 910 (Fed. Cir. 2011) 4

Lighting Ballast Control LLC v. Philips Elecs. N. Am Corp.,
No. 12-1014 (Fed. Cir. 2013) 4

McDonough v. Anoka Cty.,
No. 14-1754 (8th Cir. 2014) 9

Neonatology Associates, P.A. v. C.I.R.,
293 F.3d 128 (3d Cir. 2002) 3, 4, 5, 7

SKF USA, Inc. v. U.S. Customs & Border Prot.,
583 F.3d 1340 (Fed. Cir. 2009) 4

SkinMedica, Inc. v. Histogen Inc.,
727 F.3d 1187 (Fed. Cir. 2013) 5

Stein v. McGowan,
No. 12-cv-605, 2015 WL 268962 (S.D. Ohio 2015) 6

Wolfchild v. United States,
260 F. App'x 261 (Fed. Cir. 2007) 5

STATUTES AND RULES

Fed. R. App. P. 29 ....1, 3

Fed. R. App. P. 29(a)(3) 3

OTHER AUTHORITIES

Allison Orr Larsen, *The Trouble With Amicus Facts*,
100 VA. L. REV. 1757 (2014) 2, 5

Amgen Inc., *Learn about the different options to take Repatha*,
https://www.repatha.com/how-to-start-injection/?WT.z_co=A&WT.z_in=LDL&WT.z_ch=PDS&WT.z_st=Site1&WT.z_mt=PM&WT.z_pdskw=pushtronex&WT.z_ag=&WT.z_se=G&WT.srch=1&WT.z_prm=Branded%202016&WT.mc_id=A_LDL_PDS_G_Brand_2016_PM_pushtronex (last visited Mar. 9, 2017 10

ARGUMENT

Amici physicians and patients have fully satisfied the requirements under Rule 29 by stating their interest in the case and by providing perspectives and information that will be relevant and useful to this Court in considering the district court's decision to enjoin the sale of Praluent. Appellees have failed to set forth any legitimate reason to silence the very people who will be most impacted if the injunction that the lower court issued is not vacated. Instead, Appellees resort to calling into question the credibility of patients who simply want to continue to receive the only medication that has helped them, including an 84-year-old grandmother and a patient who—though only in her forties—already has had major heart surgery and suffered a heart attack. None of Appellees' contentions has merit and none should bar Amici's input here.

Appellees first contend that amici's motion for leave should be denied because their brief improperly supplements the record. That contention ignores Rule 29, overwhelming case law, and numerous pronouncements on the usefulness of amicus briefs that fill factual gaps for the courts. Tellingly, Appellees do not cite any authority whatsoever for the proposition that amici's brief should be rejected out of hand under the circumstances here. Instead, Appellees rely on an article that argues against the vast weight of authority that holds that "when providing specialized knowledge—filling in factual gaps for the Court—the amicus is really at its best." Allison Orr Larsen, *The Trouble With Amicus Facts*, 100 VA. L. REV. 1757, 1761 (2014).

Appellees next argue—again without a single case citation supporting their assertion—that amici's brief should be rejected because it is based on conclusory speculation. As a preliminary matter, amici's first-hand experiences are not "conclusory speculation." Amici physicians provide this Court with information and perspective based on decades of practicing medicine and their daily frontline efforts in trying to treat patients with high LDL-C levels, including by prescribing Praluent and Repatha. Amici patients provide this Court with information and perspective based on decades of suffering they have endured from the effects of debilitating hypercholesterolemia and their personal experiences in taking Praluent to reduce their dangerously high LDL-C levels. Amici seek only to provide this Court with helpful and important information and unique, first-hand perspectives on the effect that removing Praluent from the market would have on their lives, the lives of their patients, and on the lives of others similarly situated.

Nor have Appellees set forth any legitimate claim of prejudice. Amici's brief is limited to this Court's assessment of the injunction that the lower court issued and will not burden the parties or the Court.

At bottom, when weighing the public interest of the permanent injunction against Praluent, amici's views and experiences are relevant and useful and should be considered by the Court. Amici's motion to submit their brief should be granted and the Court can then decide, in the context of full briefing from the parties, whether and to what extent to credit amici's input.

I. AMICI'S VIEWS ARE DESIRABLE, RELEVANT TO THE APPEAL, AND DO NOT IMPROPERLY SUPPLEMENT THE RECORD

Appellees contend that the Court should reject amici's brief because it improperly supplements the record. (Opp. at 1.) But Appellees do not cite a single case in which an amicus brief was barred outright because it purportedly supplemented the record. Indeed, Appellees' contention ignores the requirements of Rule 29, relevant case law, and numerous pronouncements on the usefulness of amicus briefs that fill factual gaps for the courts.

Rule 29 requires only that an amicus state its "interest" and provide reasons why its brief is "desirable" and "relevant to the disposition of the case." Fed. R. App. Pro. 29(a)(3)(B); *see also Fluor Corp. & Affiliates v. United States*, 35 Fed. Cl. 284, 285 (1996) ("When a court's decision would directly affect a person or entity's rights or would set a controlling precedent regarding a claim of that person or entity, leave to file an amicus curiae brief may be allowed."). Motions for leave should be granted "unless it is obvious that the proposed briefs do not meet Rule 29's criteria as broadly interpreted." *Neonatology Associates, P.A. v. C.I.R.*, 293 F.3d 128, 133 (3d Cir. 2002). Unsurprisingly, courts readily grant leave to file amicus briefs regardless of whether they present extra-record facts.

For example, in *Neonatology Associates*, then-Judge Alito, granting a motion for leave to file an amicus brief over an opposition motion, reasoned that "[e]ven when a party is very well represented, an amicus may provide important assistance to the court" by contributing: (1) "background or factual references that merit judicial notice"; (2) "particular expertise not possessed by any party to the case"; or (3) an explanation of "the impact a potential holding might have on an industry or other group." *Id.* at 132. Accordingly, the court found that "an amicus who makes a strong but responsible presentation in support of a party can truly serve as the court's friend." *Id.* at 131.

Likewise, this Court has granted leave to file amicus briefs in numerous cases. *See, e.g.*, Order, *Lighting Ballast Control LLC v. Philips Elecs. N. Am Corp.*, No. 12-1014 (Fed. Cir. Feb. 22, 2013), ECF No. 70 (granting motions for leave to file three amicus briefs where the response asserted that the proposed amicus briefs misstated the procedural history and the facts in the underlying case); *Ladd v. United States*, 646 F.3d 910, 910 (Fed. Cir. 2011) (granting leave to file an amicus brief); *GPX Int'l Tire Corp. v. United States*, 422 F. App'x 887 (Fed. Cir. 2011) (same); *Chrysler Corp. v. United States*, 604 F.3d 1378 (Fed. Cir. 2010) (same); *SKF USA, Inc. v. U.S. Customs & Border Prot.*, 583 F.3d 1340, 1341 (Fed. Cir. 2009) (same); *Casitas Mun. Water Dist. v. United States*, 556 F.3d 1329, 1330

(Fed. Cir. 2009) (same); *Wolfchild v. United States*, 260 F. App'x 261, 264 (Fed. Cir. 2007) (same).

In support of their argument, Appellees cite only to an article and two cases from this Court that have nothing to do with amicus briefs and that stand for the unremarkable proposition that *the parties* cannot expand the record on appeal. (Opp. at 2-3 (citing Allison Orr Larsen, *The Trouble With Amicus Facts*, 100 VA. L. REV. 1757 (2014); *CW Gov't Travel, Inc. v. United States*, 163 F. App'x 853 (Fed. Cir. 2005) (non-precedential); *SkinMedica, Inc. v. Histogen Inc.*, 727 F.3d 1187 (Fed. Cir. 2013)).) Far from supporting Appellees' position, the article amply demonstrates why the Court should grant amici's motion for leave to file their brief. The article makes clear that the vast weight of authority, including the Supreme Court, not only accepts amicus briefs that contain factual material not necessarily in the record, but indeed welcomes that input. "The majority view is that th[e] expertise-providing role for the amicus curiae is a good thing"; indeed, "[t]oday it is exceedingly common, and quite often praised, for an amicus to present the Court with extra-record factual information." Larsen, *supra* at 1759, 73. The article goes on to note how Justice Breyer has praised amicus briefs containing extra-record factual information as "play[ing] an important role in educating judges" and "helping to improve the quality of our decisions." *Id.* at 1761; *see also id*. (quoting Justice Alito's observation in *Neonatalogy Associates* that "an amicus may provide important assistance to the court … [by] collect[ing] background or factual references that merit judicial notice"). In short, the vast weight of authority—including as recited in Appellee's own references—has rejected Appellee's contentions here. Appellees have provided this Court with no authority supporting their argument that amici's brief should be rejected out of hand because it purportedly improperly supplements the record.

Unable to provide this Court with any legal support for their opposition, Appellees attempt to denigrate and attack the amici physicians. Appellees first rehash an argument they made in opposing the amicus briefs filed in support of Appellants' successful motion to stay by misleadingly referencing an irrelevant defamation case involving Dr. McGowan that had nothing to do with Praluent, Repatha, or the merits of this appeal. (Opp. at 3 (citing *Stein v. McGowan*, No. 12-cv-605, 2015 WL 268962 (S.D. Ohio Jan. 21, 2015).) There is no connection between Dr. McGowan's contributions in the amicus brief and the unrelated defamation suit. Appellees' implicit contention that Dr. McGowan is not credible because she accused Appellees' expert—in a case not even involving Appellees—of violating federal law in his medical practice is disingenuous. In any event, even if a wholly unrelated litigation having nothing to do with any issue in this appeal were at all relevant to assessing Dr. McGowan's input (and it is not), that consideration would go to the weight to be given Dr. McGowan's views, not whether it should be considered at all. Moreover, six other physicians and two patients on whose behalf the amici brief is presented have no connection at all to the defamation case.

Appellees next note that Dr. Aparicio previously received funding from Appellants. (Opp. at 3-4.) As an initial matter, there is no bar against payments to or funding for an amicus in an unrelated matter. Many industry groups, including groups that routinely file amicus briefs before this Court, receive money from parties that they are supporting, although not in connection with an amicus brief. Dr. Aparicio has received no funding in connection with this appeal and has no stake in the outcome other than in ensuring the best and most effective care for his patients.

In any event, the Court is more than capable of making a decision about whether and to what extent to credit or not credit the amici's views, as is the case with every amicus brief. *See Neonatology Associates*, 293 F.3d at 133 ("[I]t is preferable to err on the side of granting leave … [and] [i]f an amicus brief that turns out to be unhelpful is filed, the [Court] … can then simply disregard the amicus brief."). Amici's motion for leave should be granted.

II. AMICI WILL PROVIDE THIS COURT WITH UNIQUE AND IMPORTANT PERSPECTIVES IN WEIGHING THE MERITS OF THE INJUNCTION ISSUED BY THE DISTRICT COURT

Appellees contend that amici's brief should be rejected because it contains only "conclusory speculation." (Opp. at 4.) But amici's personal and professional experiences are not "conclusory speculation." Amici physicians have provided this Court with information concerning the impact that the permanent injunction will have on their ability to treat their patients based on their extensive years of practicing medicine and their experiences in prescribing both Praluent and Repatha to their patients over the last eighteen months. That input, rooted in years of experience, is categorically not speculation. Likewise, amici patients' concerns about their own health being harmed if they are unable to continue to take Praluent are not speculation either. Rather, amici patients' input is based on decades of suffering from the effects of debilitating hypercholesterolemia and their recent experiences in responding positively to treatment with Praluent. Those experiences cannot be dismissed as conclusory or as speculation. Information provided by amici physicians and patients should be considered on this appeal because they are the people who would have to deal with the actual, serious consequences of removing Praluent from the market. Moreover, Appellees again cite no authority for the proposition that amici's brief should be rejected based on allegedly "conclusory" statements. Indeed, courts have rejected the notion that a motion for leave should be denied merely because statements in an amicus brief are alleged to be "conclusory." *See, e.g.*, Order, *McDonough v. Anoka Cty.*, No. 14-1754 (8th Cir. June 23, 2014), ECF No. 4167656.

With no support for their contentions, Appellees again turn to attacking the credibility of amici. Appellees, for example, contend that because the FDA approved Repatha to treat patients, amici physicians are not to be believed when they state that some of their patients have failed to respond to Repatha. (Opp. at 5.) But Appellees have no basis to question amici physicians' statements of fact about their own patients. And the specifics of the Repatha FDA approval have no bearing on observations that amici physicians made concerning their patients' clinical responses. Moreover, Appellees ignore that PCSK9 inhibitors have only recently been available on the market and, in amici physicians' views, it is important to have Praluent as an option going forward in the event that more patients fail to respond to Repatha.

Appellees next question amici physicians' concerns about switching their patients to the higher dose for Repatha and the potential risks associated with having LDL-C levels that are too low. (Opp. at 5-8.) Appellees argue that recent studies confirm the safety and benefits of very low LDL-C levels. (Opp. at 6.) But those studies are based on short-term data and cannot allay concerns about very low LDL-C over the long term. It is critically important to amici physicians that they have Praluent as a treatment option because physicians treat a patient's LDL-C to a target level (a desired LDL-C value) without going too far below that number. Amici physicians do not try to lower a patient's LDL-C level significantly below the target because of the potential risks, and there currently is no evidence from long-term trials that there is added benefit to patients having such low levels of LDL-C. Physicians like amici should have the ability to determine the proper treatment regimen for their patients.

Appellees contend that patients like amicus Ms. DeBernardo, an 84-year-old grandmother with severe hypercholesterolemia and a latex allergy, should simply seek to use Appellees' Pushtronex device to administer Repatha, which Appellees allege does not contain latex and was recently approved by the FDA. But according to Appellees' website, the Pushtronex device may only be available for the once-monthly dose of Repatha, which—even assuming Ms. DeBernardo could take—may not be effective treatment for her. https://www.repatha.com/how-to-start-injection/?WT.z_co=A&WT.z_in=LDL&WT.z_ch=PDS&WT.z_st=Site1&WT.z_mt=PM&WT.z_pdskw=pushtronex&WT.z_ag=&WT.z_se=G&WT.srch=1&WT.z_prm=Branded%202016&WT.mc_id=A_LDL_PDS_G_Brand_2016_PM_pushtronex. More significantly, Appellees offer no principled reason why Ms. DeBernardo (or Ms. Wilson or patients like them) should be forced off of effective medication, only to experiment yet again with another drug that may not be effective, that must be taken in significantly higher dosage, and that may not be readily accessible, or timely available through insurance providers.

Appellees' contention that amici should not be allowed to provide this Court with relevant and useful information concerning their experience in renegotiating insurance contracts (Opp. at 10-11) also is baseless. Amici physicians, for example, have experience in their practices with switching insurance coverage for pharmaceuticals and working with patients in doing so. Even if Appellees were correct that insurance contracts may be negotiated within 24-48 hours, patients required to switch medications and enroll in cost-sharing programs nonetheless would be needlessly and significantly burdened.

Finally, Appellees' contention that the injunction would not interfere with clinical trials rings hollow. (Opp. at 12.) Appellees do not meaningfully address the concern that amici physicians raise that patients may drop out of clinical trials if Praluent is no longer available. In addition, Appellees do not address the concern that the injunction will stifle research and innovation because there will be a significant disincentive for further research if Praluent is off the market.

Accordingly, amici respectfully request that the Court grant them leave to file their brief.

Dated: March 9, 2017

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATION, TYPEFACE REQUIREMENTS, AND TYPE-STYLE REQUIREMENTS

1. This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 27(d) because it contains 2,566 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f).

2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a) and the type style requirements of Federal Rule of Appellate Procedure 32(a). The brief has been prepared in a proportionally spaced typeface using Microsoft Office Word in 14-point Times New Roman font.

Dated: March 9, 2017

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CERTIFICATE OF SERVICE

I hereby certify that on March 9, 2017, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit by using the CM/ECF system. I certify that all participants in this case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

Dated: March 9, 2017

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